

200 898
::ODMA\MHODMA\MANAGE;2 8;1
2866.1002-003 Claims as filed
CSE/jwb
February 13, 2001



Application .: 09/782,709
Filed: February 13, 2001
Docket No.: 2866.1002-003

TECH CENTER 1600/2900

OCT 15 2001

RECEIVED

CLAIMS AS FILED
(February 13, 2001)

Originally filed with 20 claims.

1. A method for assessing the ability of a vaccine composition to stimulate a T cell response, wherein the vaccine composition comprises one or more antigens or one or more nucleic acid molecules encoding one or more antigens, said method comprising the steps of:
 - (a) contacting antigen presenting cells in culture with the vaccine composition, thereby, if one or more of the antigens or nucleic acid molecules are taken up and processed by the antigen presenting cells, producing one or more processed antigens;
 - (b) contacting the antigen presenting cells with T cells under conditions sufficient for the T cells to respond to the processed antigen; and
 - (c) determining whether the T cells respond to the processed antigen; whereby, if the T cells respond to the processed antigen, the vaccine composition is capable of stimulating a T cell response; and if the vaccine composition is capable of stimulating a T cell response;
 - (d) assessing the vaccine composition in one or more animals or human subjects.
2. The method of Claim 1 wherein the T cells are human T cells.
3. The method of Claim 2 wherein the antigen presenting cells are human antigen presenting cells.
4. The method of Claim 2 wherein the T cells are CD8⁺ T cells.
5. The method of Claim 2 wherein the T cells are CD4⁺ T cells.

6. The method of Claim 2 wherein the antigen presenting cells are selected from the group consisting of macrophages, dendritic cells and B cells.
7. The method of Claim 2 wherein the T cell response to the antigen is the release of one or more cytokines or lysis of the antigen presenting cells.
8. The method of Claim 3 wherein the T cell response to the antigen which is measured is release of one or more cytokines or stimulated formation of antibodies by B cells.
9. The method of Claim 1 wherein the antigen comprises a T cell epitope.
10. The method of Claim 9 wherein the T cells are T cell clones.
11. A method for selecting one or more vaccine compositions from among a group consisting of two or more vaccine compositions for assessment in an animal or in a human, said vaccine compositions each comprising one or more antigens or one or more nucleic acid molecules encoding one or more antigens, said method comprising the steps of:
 - (a) contacting antigen presenting cells in culture with a vaccine composition selected from among said group of vaccine compositions, thereby, if one or more of the antigens or nucleic acid molecules are taken up and processed by the antigen presenting cells, producing one or more processed antigens;
 - (b) contacting the antigen presenting cells with T cells under conditions sufficient for the T cells to respond to one or more of the processed antigens;
 - (c) determining whether the T cells respond to one or more of the processed antigens; whereby if the T cells respond to one or more of the processed

- antigens, then the vaccine composition stimulates a T cell response;
- (d) repeating steps (a), (b) and (c) with each additional vaccine composition in the group, thereby determining whether each vaccine composition stimulates a T cell response; and, if one or more of the vaccine compositions stimulates a T cell response
 - (e) selecting at least one vaccine composition which stimulates a T cell response for assessment in one or more animals or human subjects.
12. The method of Claim 11 wherein the T cells and antigen presenting cells are human cells.
13. The method of Claim 11 wherein the T cells are human T cell clones.
14. A method for selecting one or more vaccine compositions from among a group consisting of two or more vaccine compositions for *in vivo* assessment in one or more animals or human subjects, said vaccine compositions each comprising one or more antigens or one or more nucleic acid molecules encoding one or more antigens, said method comprising the steps of:
- (a) contacting antigen presenting cells in culture with a vaccine composition selected from among said group of vaccine compositions, thereby, if one or more of the antigens or nucleic acid molecules are taken up and processed by the antigen presenting cells, producing one or more processed antigens;
 - (b) contacting the antigen presenting cells with T cells under conditions sufficient to produce a T cell response to one or more of the processed antigens, thereby producing a vaccine composition-stimulated T cell response;
 - (c) measuring the vaccine composition-stimulated T cell response;

- (d) repeating steps (a), (b) and (c) with each of the remaining vaccine compositions in the group, thereby identifying the vaccine composition or compositions which stimulate the greatest T cell response;
 - (e) selecting the vaccine composition or compositions which stimulate the greatest T cell response for in vivo assessment in one or more animals or human subjects.
- 15. The method of Claim 14 wherein the T cells are human T cells and the antigen presenting cells are human antigen presenting cells.
- 16. The method of Claim 15 wherein the T cells are human T cell clones.
- 17. The method of Claim 16 wherein the T cells are CD8⁺ T cell clones or CD4⁺ T cell clones.
- 18. A method for assessing the ability of a vaccine composition comprising one or more antigens or one or more nucleic acid molecules encoding one or more antigens to stimulate a human T cell response, said method comprising the steps of:
 - (a) contacting human antigen presenting cells in culture with the vaccine composition, thereby, if one or more of the antigens or nucleic acid molecules can be taken up and processed by the antigen presenting cells, producing one or more processed antigens;
 - (b) contacting the antigen presenting cells with human T cells under conditions sufficient to produce a T cell response to one or more of the processed antigens, thereby producing a T cell response;
 - (c) measuring the T cell response; and if the T cell response is greater than a pre-selected value,
 - (d) assessing the ability of the vaccine composition to stimulate a protective T cell response in one or more animals or human subjects.

19. The method of Claim 18 wherein the T cells are CD8⁺ T cell clones or CD4⁺ T cell clones.
20. The method of Claim 18 wherein the antigen presenting cells are autologous cells.